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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,980	07/06/2001	Gillian A. Kingsbury	MPI99-131PIRNDVIAM	5076

30405 7590 10/11/2005

MILLENNIUM PHARMACEUTICALS, INC.  
40 Landsdowne Street  
CAMBRIDGE, MA 02139

EXAMINER
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JUEDES, AMY E

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/899,980	Applicant(s) KINGSBURY ET AL.	
	Examiner Amy E. Juedes, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 58-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 58, 59 and 64 is/are allowed.
- 6) ☒ Claim(s) 60-63, 65 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

1. Applicant's amendment, filed 7/6/01, is acknowledged.

Claims 1-57 have been cancelled.

Claims 58-66 have been added.

Claims 58-66 are pending, and are under examination.

2. Applicant's information disclosure, filed 7/6/01 is acknowledged, and has been considered.

Applicant states that the references have been provided in the priority application USSN 09/560,639. However, references AF-DI have not been located in the file of the priority application, and have been lined through. Applicant is invited to resubmit these references to complete the record. The Examiner apologizes for the inconvenience to the Applicant.

3. The drawings are objected to because the bands on the gels in Figs. 13-15 are not discernable. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claims are drawn to isolated polypeptides comprising amino acid residues 125 to 158 of SEQ ID NO: 13. The claims appear to be further limited by reciting that said polypeptide is encoded by a nucleic acid which

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hybridizes under certain conditions to a nucleic acid molecule that encodes SEQ ID NO: 13. It is unclear, and hence indefinite, how such hybridization limitations have any bearing on the essential structure of the claimed polypeptide, which must necessarily comprise the amino acids identified in SEQ ID NO:13.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

An isolated polypeptide further comprising a heterologous polypeptide or Ig polypeptide, where said isolated polypeptide is the polypeptide defined in claims 60, 62, or 64.

In the Preliminary Amendment, filed 7/6/01, Applicant indicates that support for the Claims 58-66 can be found on pg. 24, line 29 to page 26, line 16 and page 34, line 21 to page 36, line 21.

A review of the specification fails to reveal support for the new limitations.

At page 27, the specification discloses, that a fusion protein "comprises the polypeptide in SEQ ID NO: 13 or a fragment thereof which includes the carboxy-terminus of the polypeptide and a heterologous polypeptide." Note that the specification does not disclose a fusion protein comprising an isolated polypeptide comprising amino acid residues 125 to 158,

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100-158, 75-158, 50-158, or 25-158 of SEQ ID NO: 13, as now claimed. Neither does the specification disclose an Ig polypeptide comprising amino acid residues 125 to 158, 100-158, 75-158, 50-158, or 25-158 of SEQ ID NO: 13.

7. As detailed in section 6 above, this application adds and claims additional disclosure not presented in the priority applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02. The subsequently filed oath or declaration must refer to both the application and the amendment. See MPEP 608.04(b).

8. Claims 58-59 and 64 are allowed. Claims 58-66 are free of the art.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.  
Patent Examiner  
Technology Center 1600  
September 22, 2005

  
9/22/05  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**